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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,029	06/23/2003	Sureshchandra K. Patel		9566

23992 7590 12/06/2004

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,029

Applicant(s)

PATEL, SURESHCHANDRA K.

Examiner

Christopher R. Tate

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

The amendment filed November 1, 2004 is acknowledged and has been entered. Claims 1-20 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

The amendment filed November 1, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows.

The newly recited sentence inserted into the paragraph on page 5, lines 7-11 of the instant specification defining of "blood constipation". No objective evidence to support the validity of the newly recited definition has been provided by Applicant and, based upon a patent and non-patent literature search, this term does not appear to be recognized in the medical art (please also note that the recited definition does not make medical sense - see USC 112, second paragraph rejection below).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth in the previous Office action, it is unclear as to the actual definition of the disorder "blood constipation" (now recited in independent claims 1, 11, and 20). Please note that the definition provided in the amendment to the specification (within the paragraph on page 5, lines 7-11) is unclear as it does not appear to make medical sense - e.g., how can there be a depletion of nutrients in the blood due to the inability of the gastrointestinal tract to absorb the blood nutrients? It would seem that the inability of the gastrointestinal tract to absorb the blood nutrients would result in the opposite effect - i.e., an increased level of nutrients in the blood, not a depletion.

Claim 10 recites the limitation "The pharmaceutical composition" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

Claims 1-9 and 11-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted state of the art, in view of the Trifala IDS website references obtained from eisra.com (copyright 1998) and healthmagnets.com (first copyright 1999) for the reasons set forth in the previous Office action which are restated below.

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A composition comprising asafetida, ajwain seed, vidanga, cumin seeds, fenugreek, triphala, fennel seed, and turmeric is claimed, as well as a method of administering such a composition is claimed.

As readily admitted by Applicant, each of the claimed herbal ingredients (other than perhaps one of the three herbals found within triphala) is well known in the art to be useful in treating gastrointestinal disorders (e.g., indigestion, intestinal disorders, intestinal gas, regulating digestion, heartburn, dyspepsia) - see, e.g., pages 3-5 of the instant specification.

The cited triphala website references beneficially disclose that triphala is well known in the art to be useful in strengthening/regulating digestion and harmonizing intestinal functions - see entire website documents (in addition, although not relied upon at this time, it should be noted that several of the other website references provided in the IDS of June 23, 2003 disclose that one or more of the claimed herbal have traditionally been used in the prior art for such purpose - i.e., to treat gastrointestinal disorders).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (i.e., to treat gastrointestinal disorders) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an

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unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (such as recited in instant claim 10). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore ipso facto unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill based upon the prior art knowledge of the claimed herbals, as discussed above. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount of one of more of the claimed herbal ingredients therein and/or administering the composition to a subject for relief of such gastrointestinal disorders) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the admitted state of the art and cited website references, especially in the absence of evidence to the contrary.

Applicant's arguments have been carefully considered but are not deemed to be persuasive of error in the above rejection. Applicant argues that the combination of the claimed ingredients is not only for treating gastrointestinal disorders but also for non-gastrointestinal disorders.

However, please note that the intended use of the claimed composition (such as the recited non-gastrointestinal use recited in the preamble) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the composition disclosed by the admitted and cited prior art (see, e.g., MPEP 2112). Applicant further appears to argue unexpected results in that the combination of these ingredients within a single formula provides benefits that go beyond the merely additive effects of the ingredients themselves (including that the invention is

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classified in a crowded art and, therefore, any small step forward should be regarded as significant). However, as noted above, such unexpected (e.g., synergistic) results (e.g., resulting in the argued small step forward) are highly dependent upon specific proportions and/or amounts of particular ingredients (such as recited in instant claim 10). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *prima facie* obvious for the reasons discussed above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
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